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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/496,893	02/02/00	BROWN	S HERO-1-1089

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HM12/0606

EXAMINER
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MARSCHEL, A

ART UNIT	PAPER NUMBER
1631	2

DATE MAILED:

06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/496,893**

Applicant(s)

**Brown**

Examiner

**Ardin Marschel**

Group Art Unit  
**1631**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-29 \_\_\_\_\_ is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-29 \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because no submission of computer readable form sequences etc. has been submitted. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A sequence that comes under these rules is given on page 1, line 27, of the specification, for example.

Claims 1-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Instant claim 1, parts j)-l), require undue experimentation to practice. The human genome is estimated to contain between 50,000 to 100,000 genes, most of which have not been determined even at this time. The definition firstly of a genotype that should be studied regarding a disease out of this huge gene set has been well known in the art to take massive research, usually years, to accomplish. Even narrowing the gene selections down to thousands takes huge experimental analysis effort. Thus, firstly determining a genotype of an individual and secondly narrowing

the gene difference study down to two categories as given in step k) needs a great deal of specific information to accomplish. All of these factors support this rejection as these aspects of the instant claims requiring undue experimentation to practice. The enormity of the task is also summarized in the reference by Marsh on page S137 in the CONCLUSIONS section wherein it is stated that a new paradigm is needed to sort out the genetic basis of disease. No such genetic paradigm has been found in the instant specification that alleviates the massive analysis effort that has been required in the past for each discovery of a disease-influencing gene. This undue experimentation exists in all of the instant independent claims or claims dependent therefrom due to their dependence.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Martinez, Kauffmann et al., or Schork.

Either of Martinez, Kauffmann et al., or Schork. describes the study of various diseases via inheritance, environmental factors, etc. while suggesting the linking of these data to genetic characteristics with the ultimate goal of some type of drug etc treatment being possible. The difference between these studies and the instant claims is the usage of computer or automation practice by which to either gather patient information or transmit it to a central compilation facility. These automatic practices only replace manual activities and are not a patentable distinction as evidenced by the legal decision of In re Venner (120 USPQ 192). This legal decision at page 194, second column, item [6], states that it is well settled that providing a mechanical or automatic means to replace manual activity is not an invention. Thus, as explained further in said decision, there is no patentable distinction in replacing manual activity with an automatic means as instantly claimed.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention because Martinez, Kauffmann et al., or Schork. suggests and motivates the compilation of patient data by which to correlate patient characteristics with genetic characteristics in order to define a disease-influencing gene as instantly claimed.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 22, 2000

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER